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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/458,299	12/10/1999	JOHN FIKES	18623-014800	8698

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EXAMINER
DIBRINO, MARIANNE NMN

ART UNIT	PAPER NUMBER
1644	16

DATE MAILED: 06/30/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/458,299	FIKES ET AL.	
	Examiner	Art Unit	
	DiBrino Marianne	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *7/12/02and 9/17/01* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-40* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-40* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment [illegible]

2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____

5) ☐ Notice of Informal Patent Application (PTO-152)

6) ☐ Other

DETAILED ACTION

1. Applicant's amendments filed 7/12/02 and 9/17/01 are acknowledged and have been entered.

2. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 1-4, 7-10, 37 and 38, drawn to a peptide from Her2/neu with a supermotif for binding Class I HLA molecules/pharmaceutical composition thereof, vaccine and kit thereof, classified in Class 530, subclass 328, Class 424/185.1, Class 514, subclass 15 and Class 435, subclass 975.

Note Absent evidence to the contrary, each of the recited peptide sequences from Her2/neu possessing a specific supermotif is distinct since each ligands(s) to which each of said peptides binds is not obvious over the other set of ligand(s), i.e., HLA molecules. Therefore the instant claims 1-4, 7-10, 37 and 38 encompass GROUPS, not species.

II. Claims 20-23 and 27, drawn to a peptide from Her2/neu with a supermotif for binding Class II HLA molecules/pharmaceutical composition thereof, classified in Class 530, subclass 326 and Class 514, subclass 14, respectively.

Note Absent evidence to the contrary, each of the recited peptide sequences from Her2/neu possessing a specific supermotif is distinct since each ligands(s) to which each of said peptides binds is not obvious over the other set of ligand(s), i.e., HLA molecules. Therefore the instant claims 20-23 and 27 encompass GROUPS, not species.

III. Claims 4-6, drawn to a pharmaceutical composition comprising a nucleic acid molecule that encodes a peptide from Her2/neu with a supermotif for binding Class I HLA molecules, classified in Class 514, subclass 44.

Note Absent evidence to the contrary, each of the recited nucleic acid molecules encoding a peptide(s) sequence from Her2/neu possessing a specific supermotif is distinct since each ligands(s) to which each of said peptides binds is not obvious over the other set of ligand(s), i.e., HLA molecules. Therefore the instant claims 4-6 encompass GROUPS, not species.

IV. Claims 23-26, drawn to a pharmaceutical composition comprising a nucleic acid molecule that encodes a peptide from Her2/neu with a supermotif for binding Class II HLA molecules, classified in Class 514, subclass 14.

Note Absent evidence to the contrary, each of the recited nucleic acid molecules encoding a peptide(s) sequence from Her2/neu possessing a specific supermotif is distinct since each ligands(s) to which each of said peptides binds is not obvious over the other set of ligand(s), i.e., HLA molecules. Therefore the instant claims 23-26 encompass GROUPS, not species.

V. Claims 11, 14, 15, 18 and 19, drawn to a method for inducing CTL comprising administration of a peptide with a supermotif for HLA class I molecules/pharmaceutical composition thereof, classified in Class 424, subclass 185.1.

Absent evidence to the contrary, each of the recited peptide sequences from Her2/neu possessing a specific supermotif used in the recited method is distinct since each ligands(s) to which each of said peptides binds is not obvious over the other set of ligand(s), i.e., HLA molecules. Therefore the instant claims 11, 14, 15, 18 and 19 encompass GROUPS, not species.

VI. Claims 11-13 and 15-17, drawn to a method for inducing CTL comprising administration of a nucleic acid molecule encoding a peptide with a supermotif for HLA class I molecules/pharmaceutical composition thereof, classified in Class 514, subclass 44.

Absent evidence to the contrary, each of the recited peptide sequences from Her2/neu possessing a specific supermotif used in the recited method is distinct since each ligands(s) to which each of said peptides binds is not obvious over the other set of ligand(s), i.e., HLA molecules. Therefore the instant claims 11-13 and 15-17 encompass GROUPS, not species.

VII. Claims 28, 31, 32, 35 and 36, drawn to a method for inducing Th lymphocytes comprising administration of a pharmaceutical composition comprising a peptide with a supermotif for HLA class II molecules, classified in Class 514, subclass13.

Absent evidence to the contrary, each of the recited peptide sequences from Her2/neu possessing a specific supermotif used in the recited method is distinct since each ligands(s) to which each of said peptides binds is not obvious over the other set of ligand(s), i.e., HLA molecules. Therefore the instant claims 28, 31, 32, 35 and 36 encompass GROUPS, not species.

VIII. Claims 28-30, 32, 33 and 34, drawn to a method for inducing Th lymphocytes comprising administration of a pharmaceutical composition comprising a nucleic acid molecule encoding a peptide with a supermotif for HLA class II molecules, classified in Class 514, subclass 44.

Absent evidence to the contrary, each of the recited peptide sequences from Her2/neu possessing a specific supermotif used in the recited method is distinct since each ligands(s) to which each of said peptides binds is not obvious over the other set of ligand(s), i.e., HLA molecules. Therefore the instant claims 28-30, 32, 33 and 34 encompass GROUPS, not species.

IX. Claims 39 and 40, drawn to a method for monitoring or evaluating an immune response to a tumor or an epitope thereof in a patient having a known HLA type comprising incubating a T cell sample from said patient with a peptide/tetramer thereof from Her2/neu possessing a specific supermotif

Absent evidence to the contrary, each of the recited peptide sequences from Her2/neu possessing a specific supermotif used in the recited method is distinct since each ligands(s) to which each of said peptides binds is not obvious over the other set of ligand(s), i.e., HLA molecules. Therefore the instant claims 39 and 40 encompass GROUPS, not species.

3. The GROUPS encompassed by (I and II) and (III and IV) are different products.

Peptides and nucleic acid molecules are distinct because their structures are different, which require non-coextensive searches.

4. The GROUPS encompassed by I and II are different products.

Peptides that bind to class I molecules and peptides that bind to class II molecules are distinct because they are different lengths, they bind to different classes of HLA molecules and induce different immune responses.

5. The GROUPS encompassed by III and IV are different products.

Nucleic acid molecules that encode peptides that bind to class I molecules and nucleic acid molecules that encode peptides that bind to class II molecules are distinct because the peptides they encode are different lengths, they bind to different classes of HLA molecules and induce different immune responses.

6. The GROUPS encompassed by V and VI are different methods of use.

These inventions require different ingredients and process steps to accomplish the use of inducing a CTL response, comprising using either a peptide/pharmaceutical composition thereof (V) or a nucleic acid molecule encoding said peptide/pharmaceutical composition thereof (VI).

7. The GROUPS encompassed by VII and VIII are different methods of use.

These inventions require different ingredients and process steps to accomplish the use of inducing a Th response, comprising using a pharmaceutical composition comprising either a peptide (VII) or a nucleic acid molecule encoding said peptide thereof (VIII).

8. The GROUPS encompassed by (V and VI) vs (VII and VIII) are different methods of use.

These inventions require different ingredients and process steps to accomplish the use of inducing a CTL response(V and VI) or of inducing a Th response (VII and VIII), which involve activation and proliferation of different cell types and cytokine profiles.

9. The GROUPS encompassed by (IX) vs (V, VI, VII and VIII) are different methods of use.

These inventions require different ingredients and process steps to accomplish the use of monitoring or evaluating an immune response vs the use of inducing an immune response. For example, the method of IX involves incubating a T cell sample from a patient with a peptide/tetramer thereof and detecting the presence of a peptide specific T lymphocyte, whereas the methods of V, VI, VII and VIII involve inducing a CTL or Th response in a patient.

Therefore they are patentably distinct.

10. Inventions I and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)).

In the instant case, the product as claimed can be used in a materially different process such as immunopurification procedures or detection assays.

11. Inventions III and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)).

In the instant case, the product as claimed can be used in a materially different process such as detection assays.

12. Inventions II and VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)).

In the instant case, the product as claimed can be used in a materially different process such as immunopurification procedures or detection assays.

13. Inventions IV and VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)).

In the instant case, the product as claimed can be used in a materially different process such as detection assays.

14. Inventions (I, II, III, IV) and IX are related as product(s) and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)).

In the instant case, the product(s) as claimed can be used in a materially different process such as immunopurification procedures or detection assays.

15. Because these inventions are distinct for the reasons given above and the search required for any GROUP encompassed by I-IX is not required for any other GROUP encompassed by I-IX and I-IX have acquired a separate status in the art as shown by their different classification

16. It is noted that the instant claims encompass a specific peptide/composition, kit, vaccine, tetramer thereof, possessing a specific supermotif or nucleic acid encoding said peptide or a method of using the said peptide or nucleic acid molecule. **Irrespective of whichever group Applicant may elect**, Applicant is further required to (1) elect a single disclosed species (a ***peptide possessing a specific HLA supermotif or nucleic acid encoding said peptide***, for example, Applicant is required to elect a specific peptide or a specific nucleic acid molecule encoding the said peptide for the product or method of the instant claims, i.e., a specific sequence from one of the Tables recited in the instant claims) to which claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

These species are distinct because their structures are different.

17. Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

18. Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

19. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

20. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

21. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

22. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the

23. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Marianne DiBrino whose telephone number is 703-308-0061. The examiner can normally be reached on Monday, Wednesday and Friday afternoons.

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Christina Chan, can be reached on (703) 308-3973. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.
Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

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Group 1640
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June 26, 2003

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